

## **REMARKS**

### **Status of the claims**

Claims 6 and 10-20 are pending in the present application, with claim 20 being newly added. Claims 12, 13, 14 and 19 are amended herein. No new matter has been added with the new claim or amendments.

### **Statement of the Substance of the Interview**

The Interview Summary issued by the Examiner effectively sets for the nature and discussion of the Interview of May 19, 2009.

### **Issues under 35 U.S.C. § 112**

Claims 12-13 and 17-19 under 35 U.S.C. 112, second paragraph, as being indefinite. More specifically, the Examiner asserts that claim 12 is vague in the recitation of "peptide consisting of any one of SEQ ID NOS:4-12 or 14-17 and one or more additional amino acids of SEQ ID NO:1".

Claim 12 has been further rejected for recitation of "a ratio" because it is not clear if the ratio is between any two of the peptides of SEQ ID NOS:4-12 or 14-17 or another ratio.

Claims 13 and 19 have been rejected with the assertion that an essential step is omitted, which is a final step that leads to the identification of a therapeutic agent AD as stated in the preamble of the claims.

Claim 18 has been rejected as not making sense with regard to the recitation of "a first peptide" with the assertion that claim 10, from which claim 18 depends, does not recite "a first peptide". Applicants respectfully note that claim 18 recites "a first peptide" not "the first peptide". As such, antecedent basis for this feature does not need to be found in claim 10.

Claims 12, 13 and 19 have been rejected with the assertion that claim 6 is not limited to the use of one peptide, therefore recitation of “the peptide” is indefinite. Applicants respectfully note that claim 6 recites “An isolated peptide”. As such, antecedent basis is provided in claim 6 for recitation of “the peptide” in claims 13 and 19. In addition, claim 12 does not depend from claim 6. As such, the rejection of this claim is also in error.

The rejections have been addressed and/or the claims have been amended as indicated above to address the rejections and clarify the metes and bounds of the claims. Withdrawal of the rejections is therefore respectfully requested.

**Rejections under 35 U.S.C. §112, 1<sup>st</sup> paragraph**

Claims 12-13 and 17-19 have been rejected under 35 U.S.C. §112, 1<sup>st</sup> paragraph for lacking enablement. As Applicants explained during the interview of May 19, 2009, the disclosure in the specification beginning at page 15 and Examples 11 and 12 support enablement of the claims. The specification clearly explains that it is expected that the peptides of SEQ ID NOS: 4-12 and 14-17 will be markers for the diagnosis and prognosis of Alzheimer’s disease. In addition, the experiments in the specification demonstrate that the molecular weight of the peptide fragment increases in a cellular model for Alzheimer’s disease.

The Examiner is basing her position, in part, on an asserted difficulty in the field of Alzheimer’s Disease (AD) with regard to identifying suitable drugs and treatment and/or diagnosis. In view of this, the Examiner finds that the *in vitro* experiments of Examples 11 and 12 are insufficient to enable the method of diagnosis of claims 12 and 18, and the methods of screening for a therapeutic agent of claims 13, 17 and 19. The Examiner further noted that there is no evidence that the high molecular weight peptides actually occur *in vivo* in AD.

Applicants traverse this rejection and withdrawal thereof is respectfully requested. The Examiner has asserted many technical points regarding the state of the art; however none of these asserted points are supported by any evidence. Thus, the Examiner appears to be taking

“official notice” with regard to her position. However, as unequivocally stated in MPEP §2144.03,

“Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known... It is never appropriate to rely solely on “common knowledge” in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697 (“[T]he Board cannot simply reach conclusions based on its own understanding or experience or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.”)”

Applicants do not simply assert the enablement of the invention without any evidence. The specification provides examples in a cellular model which are indicative of the enablement of the invention for the diagnosis and prognosis of Alzheimer’s disease. These experiments further support the use of the ratio of a higher molecular weight fragment of SEQ ID NO:1 compared to a peptide of SEQ ID NOS:4-12 or 14-17, which is of lower molecular weight; or a change in such ratio as a diagnostic for Alzheimer’s disease. The MPEP also clearly states that “If applicant adequately traverses the examiner’s assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained.” The court has similarly stated that “It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi and Horton*, 169 USPQ 367 (CCPA 1971) (emphasis added). While the Examiner has explained why she doubts the adequacy of the specification, she has failed to provide any supporting evidence of her position. As such, Applicants respectfully request that either the rejection be withdrawn or sufficient evidence in support of the Examiner’s position be provided.

**Rejections under 35 U.S.C. §102**

Claim 6 has been rejected under 35 U.S.C. §102(b) as being anticipated by Sonderegger et al. During the interview and in the Office Action, the Examiner maintains that claim 6 is anticipated by Sonderegger et al. because claim 6 allegedly encompasses the recited sequences with any amount of additional amino acids. Sonderegger et al. is relied on for disclosing a protein having at least amino acids 820-838 of SEQ ID NO:1. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

During the interview, the Examiner stated that she interprets “consisting essentially of” as meaning the same thing as “comprising”, i.e. completely open such the that claims encompass the recited sequences with any amount of additional amino acids. Thus, the Examiner asserts that claim 6 includes SEQ ID NO:2 of Sonderegger et al. However, the Examiner is legally incorrect in her position. The MPEP states in §2111.03 that “The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention.” The MPEP further states that “For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.”” Thus, Applicants agree that under certain circumstances, “consisting essentially of” may be equated with “comprising”. However, claim 6 does not fall under such circumstances. It is unequivocally clear from the specification that enlarging the sequences of SEQ ID NOS: 4-12 and 14-17 so as to encompass the full sequence of Sonderegger et al. would render SEQ ID NOS:4-12 and 14-17 unsuitable for their intended use, i.e. materially affect the invention. As such, “consisting essentially of” cannot be interpreted, for claim 6, as meaning “comprising”. Claim 6 does not therefore, encompass the sequence of Sonderegger et al. and withdrawal of the rejection is respectfully requested.

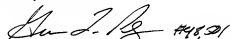
In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, Ph.D., Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: AUG 4 2009

Respectfully submitted,

By  #40,069

MaryAnne Armstrong, Ph.D.

Registration No.: 40,069

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant